REMARKS

Applicants thank the Examiner for pointing out the error pertaining to the "claims pending" and for allowing applicants the opportunity to correct the error.

New independent claim 81 has been added to this application, and dependent claims 82-83 have been added because those claims had previously been inadvertently canceled. Claims 58 and 64 have now been canceled to eliminate the issue previously raised by the Examiner. The claims that are now pending in this application therefore are 33, 35-57, 60-63, and 66-83. To assist in the examination of this application, applicants have furnished the Examiner with a complete copy of the claims that are pending in this case (see Appendix).

The double patenting rejection cannot be sustained for the reasons presented in applicants' Amendment submitted April 26, 2002.

Claims 33, 35-46, 47, 48-57, 59, and 66-80 have been rejected under 35 USC § 103 as being unpatentable over UK Patent 2,072,516 to Simpson in combination with U.S. Patent 3,191,618 to McKim. Applicants respectfully submit that this rejection cannot be sustained.

Applicants' invention pertains to a filtering face mask 10 that comprises a mask body 12 that is adapted to fit over the nose and mouth of a wearer. The filtering face mask 10 also has an exhalation valve 14 that is attached to the mask body 10. This exhalation valve can be attached to the mask body directly in the path of the exhale flow stream. The exhalation valve comprises a valve seat 26 and a single flexible flap 24. The valve seat 26 includes a seal surface 31 and an orifice 32. The flexible flap 24 has a stationary or fixed portion 28 and only one free portion. The stationary portion 28 remains at rest during an exhalation, and the free portion is lifted away from the seal surface 31 during an exhalation. The free portion can be located below the stationary portion when the filtering face mask is worn on a person. A valve of this type of construction is commonly referred to as a "flapper" or "cantilevered" valve, as opposed to the commonly used button-style valves (see, for example, Figure 3 of Simpson), which have the whole peripheral edge of the flap free to be lifted from the valve seat. In applicants' flapper valve, the flexible flap would normally assume a flat configuration when no forces are applied to it, but the flap has a curved profile when viewed from the side in its secured position on the valve seat and is pressed towards the seal surface 31 in an abutting relationship with it when a fluid is not passing through the orifice.

Simpson describes a flap valve 13 in its Figure 2 that comprises a flexible circular flap member 15:

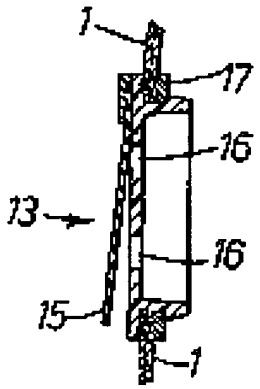


FIG. 2.

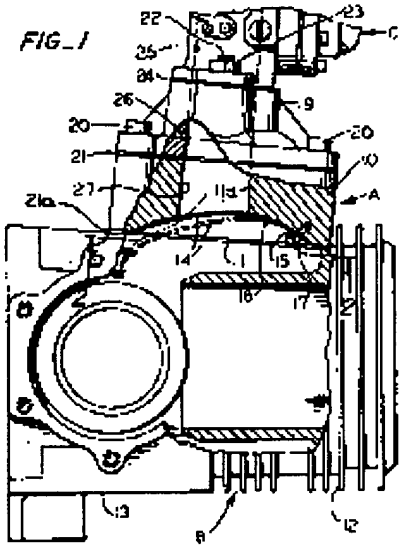
[Simpson]

The flap member 15 is made of a plastic material and is arranged to cover a closed valve opening 13 during an inhalation and to flex away from those openings during an exhalation (p. 2, lines 37-42). To allow flexing of the flap member 15, a part of its peripheral portion — that is, a segment of the flap member — is fixed in position and the remaining part of the flap member is left free (p. 2, lines 42-46). The valve is fitted in an aperture on the mask and is held in place by a retaining ring 17 (p. 2, lines 46-50). As shown in Simpson's Figure 1 reproduced above, the valve 12 is disposed on the top portion 1 of Simpson's duck-bill or pouch-shaped mask.

The combination of Simpson and McKim would not have rendered applicants' invention obvious to a person of ordinary skill for the following reasons.

1. McKim is Not Analogous Art

The secondary reference, U.S. Patent 3,191,618 to McKim, cannot be applied as a reference against applicants' invention because the McKim patent does not reside in an analogous art. McKim discloses a curved seat reed valve for a 2-cycle engine:



[McKim]

The reed valve includes a valve reed 14 of spring sheet materials such as shim stock (col. 1, lines 60-61). The spring sheet material is secured by an anchor bar 15 and screws 17 to a curved seat 18 that is formed on the inner-engine side of the valve bock 10 (col. 1, lines 61-63). Curvature of the seat 18 corresponds to the normally flexed condition of the valve reed 14 when it is flexed laterally from its normally straight position as shown in Figure 3 (col. 1, lines 64-66). The normally flexed curvature of the reed is provided to eliminate float, or flutter from bounce when closing (column 1, lines 19-24; column 2, lines 55-62). The McKim valve is fashioned for use on high-speed engines, for example one that will turn at a speed on the order of 10,000 to 12,000 revolutions per minute (col. 2, lines 55-62). For a more modest speed, for example, 5,000 or 6,000 rpms, the curvature of the valve seat may be reduced to provide a freer, fuller opening of the valve at the lower speeds (column 2, lines 62-65).

As the Examiner is aware, a reference is not analogous and thus not relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.[1] Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed intake valves. McKim

[1] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

therefore does not satisfy part (1) of the two-part test. Thus, we only need to evaluate McKim under part (2) of the test.

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit has explained that the USPTO needs to consider the purposes of both the cited disclosure and the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).[2]

In developing their invention, applicants sought to produce an exhalation valve that minimized exhalation pressure needed to open the valve and that allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort while also allowing the valve to remain closed under any orientation (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure so that a greater percentage of exhaled air can be purged from the mask interior while also enabling the valve to remain closed under any orientation. As stated in the Bowers Declaration, investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

[2] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

> In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

Bowers' Declaration, paragraphs 11-13. Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

> My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.
>
> In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a

reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001).

The Bowers and Fabin declarations discussed above explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of applicants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A person possessing ordinary skill in the art of filtering face masks that use exhalation valves therefore would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce in a valve reed in a 2-cycle gasoline engine.

The Federal Circuit has clearly stated that when the reference "is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it" and

therefore it would not be analogous.[3] **Accordingly, since the Examiner cannot establish that eliminating float or bounce is a purpose of applicants' invention, McKim cannot qualify as an analogous reference, and therefore the rejection based on McKim must be withdrawn.**

In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation (to channel flow in a desired direction) and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although both Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved; namely, preventing loss of stored product in a tank's dead volume. The court also found that the subterranean formation of Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.

As in *In re Clay*, the McKim reference also does not have the same purpose as the applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce is a problem that occurs when a two-cycle engine operates at high rpms (10,000 to 12,000 rpms). It is not a problem that occurs in an exhalation valve that opens and closes in cadence with a person's breathing, which is about 20 to 60 cycles per minute. And internal combustion engines, of course, operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Further, McKim's valve is used for intake while the present valve is used for exhaust.

[3] *Id.*

Applicants accordingly encourage the Examiner to carefully consider the *In re Clay* decision.[4] A summary of the facts are provided below for ease of reference:

[4] *See also, SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177 (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

In re Clay	**Result: reference not analogous**					
	Description	***Problem to be Solved***	***Purpose***	***Operating Conditions***	***Similarities***	***Differences***
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	• subterranean rock • high temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	• made storage tank • ambient temp and pressure		
In re Japuntich et al.	**Result: not yet decided**					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	• exhale valve on face mask body • body temperatures • low pressures • cadence of person's breathing	both relate to valves	different purposes and operating under different temperatures, pressures, and speeds
McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	• intake valve on 2-cycle engine • high temps • high pressure • high speeds (10-12,000 rpms)		

2. McKim Does Not Describe a Flexible Flap

Even if McKim is found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of applicants' valve. As such, there would be no expectation, on the part of a person of ordinary skill, that McKim's teachings would be suitable for use on an exhalation valve.

There is no evidence that the McKim reed valve can demonstrate the required flexibility of applicant' flexible flap. Applicants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever, exposed to

gravity, and viewed from a side elevation (see, e.g., Fig. 6)."[5] The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve.[6] This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different — namely, so much stiffer than — the flexible flap that is used in applicants' invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for use with a flexible flap of an exhalation valve. As stated by Betts in his Declaration, if secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation." Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) are so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable in an invention like the one under consideration here. Thus, the

[5] Applicants' specification at page 7, lines 11-14.

[6] In an interview held with Examiner Lewis and the SPE Examiner Weiss in another continuation application in this series, Examiner Weiss agreed with applicants' attorney that a reed valve in a 2-cycle engine would not be flexible like the flap of the present invention.

mounting requirements for the McKim cannot so easily be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so.

3. No Evidence of Teaching of Suggestion to Combine McKim with Simpson

The record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Examiner is also aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.[7] The suggestion to make the combination must come from the prior art.[8] It is not enough to simply identify each claimed element in the prior art.[9] "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."[10]

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved intake reed valve seat on a 2-cycle gasoline engine to reduce float or bounce. Nonetheless, the Examiner stated in the Office Action mailed July 17, 2002, that "it would have been obvious to modify the flexible valve flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick seating, in an effective manner and without float or bounce after each opening as taught by McKim." **The Examiner, however, has not cited any authority for his view that eliminating float or bounce would have been a problem that persons skilled in the art of designing exhalation valves would have sought to overcome.** The burden showing evidence of a teaching

[7] *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").
[8] *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").
[9] *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").
[10] *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

or suggestion to combine therefore has not been met. Although not necessary to overcome the rejection, applicants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers stated that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, the "bounce or float" motivation cited in the Office Action for combining the two references does not exist and the burden of supplying the record with evidence of a suggestion to combine has not been satisfied.

4. Evidence of Record Suggests Combination is Not Proper

The Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the use of a curved flexible flap, and the particular structure necessary for creating that curvature and causing the flap to be pressed towards the seal surface, would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's.

The Examiner should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this time span. If this aspect of the applicants' invention would have been obvious to a person of ordinary skill, then the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.[11]

[11] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic'

Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[12]

In addition, Simpson, while recognizing that its valve may leak, suggests using an "antechamber" as a solution (p. 1, lines 58-64). Simpson does not suggest modifying this valve in the manner described by applicants. This presents very good evidence of the non-obviousness of the combination. And, to the extent that the Simpson valve does not remain closed under any orientation, this fact presents further evidence of nonobviousness.[13] As the record presently stands, therefore, only applicants describe a low pressure drop, cantilevered valve that is capable of sealing effectively under any orientation. Applicants' teachings, of course, cannot be properly used against them to reject their own invention. Accordingly, until sound evidence is placed in the record, the present combination cannot be properly sustained.[14]

---

referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

[12] *See In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

[13] *In re Dien*, 152 USPQ 550, 551 (CCPA 1967) ("The mere existence ... of an unsatisfactory process and the attendant incentive to seek improvement do no negative patentability.').

[14] *See, Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.

5. Prior Art Fails to Suggest Advantage of Applicants' Invention

An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103.[15] Advantages that are not appreciated by the prior art also provide very good evidence of nonobviousness.[16] In the present case, applicants' invention possesses the benefit of achieving a low pressure drop valve while also preventing the influx of contaminants through the valve under any orientation. The Simpson valve, however, only protects the wearer at the most critical time — during an inhalation. When a wearer of either mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson's valve therefore may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson mounts its valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted to the underside of the mask, the flap would dangle away from the seal surface. The Simpson valve, unlike applicants' invention, therefore, have limited suitable mounting positions on the mask body when considering the need to halt contaminant influx under neutral conditions. But even if either valve was mounted to the top of the mask body to take advantage of gravity for this purpose, they still could allow contaminants to enter the mask interior when the user fully tilts their head downward. Further Simpson does not teach or suggest valves that have a pre-load on the flap. As such, these valves can remain open when moisture of saliva causes the flap to stick to another surface like a valve cover.

Applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. Applicants achieve this through the use of a single flexible flap that has one free portion, one stationary portion, and a peripheral edge, where the peripheral edge has a stationary and free segments which are associated, respectively, with the stationary and free portions of the flap, and through use of a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice

[15] *In re Papesch*, 137 USPQ 43 (CCPA 1963).
[16] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

under any orientation of the valve. Applicants' valve also does not have to be disposed on the top side of the mask, and there is little risk that the flap will get stuck in the open position. Applicants' invention enables the valve to be disposed on the mask directly in the path of the exhale flow stream — that is, centered on the front of the mask directly in front of where the wearers would be when the mask is worn (see Fig. 1) — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface. This encourages a substantially larger percentage of air to pass rapidly through the exhalation valve. It also may allow an aspiration effect to occur, which further improves wearer comfort.[17] The aspiration effect is a truly remarkable achievement since it allows cool ambient air to be drawn into the mask interior during an exhalation.

As indicated in paragraphs 15 and 16 of the Bowers Declaration, the Simpson flap would droop open when the wearer tilts their head downward:

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.
>
> The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The failure of Simpson to appreciate the benefits of applicants' invention and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. McKim, of course, does not address these benefits to the slightest degree because it is a reference that resides in an entirely different field and deals with entirely different problems under entirely different conditions. In short, the prior art does not teach or suggest the construction of applicants' valve, and it does not appreciate the benefits that that construction invention can provide. Under

[17] *See* applicants' specification at pp. 20-23.

such circumstances, Simpson and McKim would have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.[18]

6. Evidence of Copying Shows Nonobviousness

The copying of the technology of applicants' invention shortly after its publication further establishes its non-obviousness. As the Examiner is aware, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.[19] For example, in *Specialty Composites v. Cabot Corporation,*[20] the Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."[21] Secondary considerations like copying must always be considered in connection with an obviousness determination.[22]

An examination of this article reveals a cantilevered flexible flap that is curved and is pressed towards the seal surface in a substantial abutting relationship with it. This product is described in U.S. Patent 6,047,698 to Magidson et al., which was filed on August 20, 1998, after applicants' invention was publicly disclosed. But Moldex' earlier reveals that button-style valves were used on Moldex' filtering face masks (see U.S. Patent 4,873,972). And the more recent '698 Magidson patent (which describes the Exhibit C valve) states the benefits of using the technology claimed in this patent application:

> The valve member 16 includes an off center arm 24 which cooperates with a shelf portion 26, located within the valve seat 22, to lock the flexible flap 20 off

[18] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).
[19] See e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper weight."); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F. 2d 617, 622, 2 USPQ2d 1350, 1355 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 849 (1987) (the conclusion that the claimed invention would not have been obvious is supported by evidence of commercial success and acts of the infringer in trying but failing to "develop the claimed invention and [then copying] it instead"); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").
[20] 6 USPQ2d 1601, Fed. Cir. 1988.
[21] *Id.* at 1608.
[22] *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).

center in position within the valve 14 when the two half members 16 and 18 are closed, as shown by arrow 28, around a hinge portion 30.

(Column 2, lines 15-21). The '698 Moldex patent goes on to state that the flap is pushed into sealing engagement with the valve seat when a fluid is not passing through the orifice. Moldex illustrates the technology in Figs. 3 and 4:

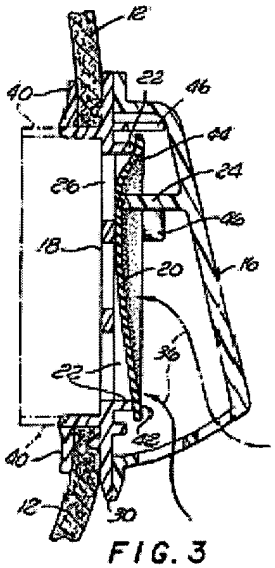


FIG. 3

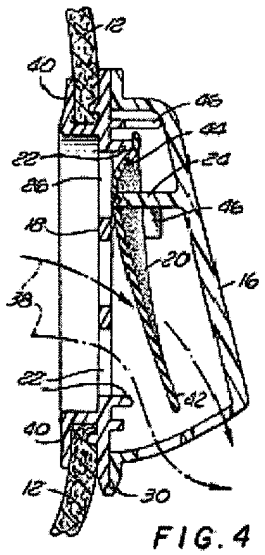


FIG. 4

Another product of similar structure, which also was introduced after the publication of applicants' invention has been sold by Survivair.

The use of the technology of applicants' invention by other respiratory product manufacturers after publication of applicants' invention provides very good evidence that the invention would not have been obvious to a person of ordinary skill. Although Simpson's teachings had been known for many years before applicants' filing date, there is no evidence that any competitor had previously introduced a product that is similar to the exhalation valve that is described and claimed in the present application. The introduction of such products after the publication of the technology of applicants' invention, however, further establishes that person's skilled in the filtering face mask art surely did not find obvious the subject matter of applicants' invention.

Rejection of Claims 60-63

The Examiner has also rejected claims 60-63 as being unpatentable over Simpson in view of McKim and further in view of U.S. Patent 812,706 to Warbasse and U.S. Patent 4,934,362 to Braun. Applicants respectfully submit that this rejection cannot be sustained.

Although U.S. Patent 812,706 to Warbasse (published in 1906) has been referenced for teaching a valve cover that has a fluid-impermeable ceiling that increases in height in the direction of a flexible flap from a first end to the second end, Warbasse does not suggest the use of its valve cover on an exhalation valve that is used in a filtering face mask that is adapted to fit over the nose and mouth of a person. Warbasse describes a device that is placed over a person's nose and is connected to a supply line tube 16. No teaching or suggestion has been identified, which would have motivated a person of ordinary skill to use Warbasse's hood element 11 in the Simpson valve shown in Figure 2. The Examiner indicates that "it would have been obvious to modify the valve (figure 2) of Simpson et al. to provide a valve in this (fig. 2) to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse." Although there may be a variety of reasons for using a valve cover on the valve shown in Simpson, *the Examiner has not yet identified any particular suggestion of why a person of ordinary skill would have selected the hood element 11 in Warbasse's nose device for use on the exhalation valve shown in Figure 2 of Simpson.* As the Examiner is aware, the United States Patent and Trademark Office has the burden of providing *evidence* that shows why a person or ordinary skill would have combined the teachings in two different references. Mere conclusory statements generated by the Examiner do not qualify as evidence. In this regard, the Examiner's attention is again directed to *In re Lee* where the Federal Circuit explained that the motivation to combine references is a factual question that cannot be resolved on subjective beliefs of unknown authority.[23]

The Examiner states that the reasons for combining Warbasse with Simpson are taught in Warbasse. *But a review of this patent reveals that none of these reasons can be found anywhere in Warbasse.* Some of those reasons, however, can be found in applicants' specification. For

[23] *See In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) ("This factual question of motivation [to combine the references] is material to patentability and could not be resolved on subjective belief and unknown authority.").

example, applicants state that the exhalation valve, "can be provided with a valve cover to protect the flexible flap" (see applicants specification, page 14, lines 33-35). Applicants also explain that the valve cover can allow the exhaled air to be "directed downwards to prevent fogging of the wearer's eyewear" (see applicants' specification at page 15, lines 5-8). It is, of course, improper to use applicants teachings against them in attempting to establish that a person of ordinary skill would have been led to the combination of references.[24] The record therefore does not establish why a person of ordinary skill would have been motivated, in particular, to use Warbasse's hood element 11 on Simpson's valve over any of the multitudes of value covers that have been previously described in the art.

The Braun patent adds little or nothing to the disclosure that is lacking in Simpson and McKim with respect to claims 60-63. The Braun patent does not teach or suggest a valve cover that has a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end. To the contrary, *Braun does not even teach or suggest a fluid-impermeable ceiling. Braun only describes a grill 25, and this grill 25 does not have a fluid-impermeable ceiling that increases in height* in the direction of the flexible flap from its first end to its second end. To the contrary, the grill 25 is located closer to the free end of the flap 24 relative to its fixed portion located at 19. Under such circumstances, Braun teaches away from applicants' invention and also provides very good evidence that the subject matter of claims 60-63 would not have been obvious to a person of ordinary skill.

Respectfully submitted,

January 31, 2003
Date

By: _____
Karl G. Hanson, Reg. No. 32,900
Telephone No.: (651) 736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

[24] *In re Lee*, 61 USPQ2d at 1434 ("It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.'"; *see also, W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983).

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Specification Amendment

Page 7, please replace the paragraph beginning at line 15 and ending at line 26 with the following paragraph:

When a wearer of a filtering face mask **10** exhales, exhaled air passes through the mask body **12** and exhalation valve **14**. Comfort is best obtained when a high percentage of the exhaled air passes through exhalation valve **14**, as opposed to the filter media of mask body **12**. Exhaled air is expelled through valve **14** by having the exhaled air lift flexible flap **24** from valve seat **26**. Flexible flap **24** is attached to valve seat **26** at a first portion **28** of flap **24**, and the remaining circumferential edge of flexible flap **24** is free to be lifted from valve seat **26** during exhalation. As the term is used herein, "flexible" means the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever, exposed to gravity, and viewed from a side elevation (see e.g., FIG. [5] 6). A flap that is not self-supporting will tend to drape towards the ground at about 90 degrees from the horizontal.

Claim Amendments

33. (twice amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is circumscribed by the seal surface; and

(iii) cross members that extend across the orifice to create a plurality of openings within the orifice; and

(2) a single flexible flap that has a fixed portion and only one free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces are applied to it, but the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice.

61. (amended) The filtering face mask of claim 60 [61], wherein the opening in the valve cover is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

62. (amended) The filtering face mask of claim 60 [61], wherein the valve cover and its opening direct exhaled fluid flow downwards when the mask is worn on a person.

63. (amended) The filtering face mask of claim 62 [63], wherein the valve cover has fluid-impermeable sidewalls.

66. (amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is circumscribed by the seal surface;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and a free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the non-central stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free portion also being located below the non-central stationary portion when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed without a fluid passing through the orifice, the flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith.

67. (amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is surrounded by the seal surface when viewing the valve seat from the front;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the non-central stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the only one free portion also being located below the non-central stationary portion when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed without a fluid passing through the orifice, the single flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith.

APPENDIX

Claims Pending As of January 31, 2003

33. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is circumscribed by the seal surface; and

(iii) cross members that extend across the orifice to create a plurality of openings within the orifice; and

(2) a single flexible flap that has a fixed portion and only one free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces are applied to it, but the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice.

35. The filtering face mask of claim 33, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

36. The filtering face mask of claim 35, wherein the valve seat has been made by an injection molding technique.

37. The filtering face mask of claim 33, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

38. The filtering face mask of claim 37, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

39. The filtering face mask of claim 37, wherein the flexible flap is made from an elastomeric rubber.

40. The filtering face mask of claim 33, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

41. The filtering face mask of claim 40, wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 C.F.R. § 11.183-2, July 1, 1991.

42. The filtering face mask of claim 33, wherein the flexible flap is made from a crosslinked polyisoprene.

43. The filtering face mask of claim 33, wherein the flexible flap has a Shore A hardness of about 30 to 50.

44. The filtering face mask of claim 33, wherein the flexible flap has a generally uniform thickness of about 0.2 to 0.8 millimeters.

45. The filtering face mask of claim 44, wherein the flexible flap has a generally uniform thickness of about 0.3 to 0.6 millimeters.

46. The filtering face mask of claim 45, wherein the flexible flap has a generally uniform thickness of about 0.35 to 0.45 millimeters.

47. The filtering face mask of claim 33, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

48. The filtering face mask of claim 47, wherein the flexible flap is greater than one centimeter wide.

49. The filtering face mask of claim 48, wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

50. The filtering face mask of claim 33, wherein the fixed portion of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

51. The filtering face mask of claim 33, wherein the valve seat includes a flange that provides a surface onto which the exhalation valve can be secured to the mask body, and wherein the flange extends 360 degrees around the valve seat where the valve seat is mounted to the mask body.

52. The filtering face mask of claim 33, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

53. The filtering face mask of claim 33, wherein the mask body is cup-shaped and comprises (1) at least one shaping layer for providing structure to the mask, and (2) a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

54. The filtering face mask of claim 33, wherein a high percentage of the exhaled air is purged through the exhalation valve.

55. The filtering face mask of claim 33, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

56. The filtering face mask of claim 55, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

57. The filtering face mask of claim 33, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

60. The filtering face mask of claim 33, which mask further comprises:

a valve cover that is disposed over the valve seat and that comprises:

(i) an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation;

(ii) a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and

(iii) cross members that are disposed within the opening of the valve cover.

61. The filtering face mask of claim 60, wherein the opening in the valve cover is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

62. The filtering face mask of claim 60, wherein the valve cover and its opening direct exhaled fluid flow downwards when the mask is worn on a person.

63. The filtering face mask of claim 62, wherein the valve cover has fluid-impermeable sidewalls.

66. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is circumscribed by the seal surface;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and a free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the non-central stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free portion also being located below the non-central stationary portion when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed without a fluid passing through the orifice, the flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith.

67. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is surrounded by the seal surface when viewing the valve seat from the front;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the non-central stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the only one free portion also being located below the non-central stationary portion when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed without a fluid passing through the orifice, the single flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith.

68. The filtering face mask of claim 67, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

69. The filtering face mask of claim 67, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

70. The filtering face mask of claim 67, wherein the flexible flap is made from an elastomeric rubber that has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C, and wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 C.F.R. § 11.183-2, July 1, 1991.

71. The filtering face mask of claim 70, wherein the flexible flap is made from a crosslinked polyisoprene.

72. The filtering face mask of claim 67, wherein the flexible flap has a Shore A hardness of about 30 to 50, and has a generally uniform thickness of about 0.3 to 0.6 millimeters.

73. The filtering face mask of claim 67, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface, and wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

74. The filtering face mask of claim 67, wherein the fixed portion of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

75. The filtering face mask of claim 67, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

76. The filtering face mask of claim 67, wherein the mask body is cup-shaped and comprises at least one layer for providing structure to the mask and a filtration layer, the at least one structure-providing layer being located outside of the filtration layer.

77. The filtering face mask of claim 67, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

78. The filtering face mask of claim 67, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

79. The filtering face mask of claim 67, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

80. The filtering face mask of claim 67, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

81. A filtering face mask that comprises:

(a) a substantially cup-shaped mask body that is fluid permeable, contains a layer of filter media, and is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is surrounded by the seal surface when viewing the valve seat from the front;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and only one free portion and a peripheral edge that includes a free segment, the non-centrally disposed stationary portion of the flap remaining essentially stationary during an exhalation, and the free segment of the peripheral edge being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed when a fluid is not

passing through the orifice, the single flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the mask.

82. The filtering face mask of claim 33, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

83. The filtering face mask of claim 60, wherein the opening in the valve cover is at least the size of the orifice in the valve seat.